IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
HATTIESBURG DIVISION

JAN HUGHES PLAINTIFF

VERSUS CIVIL ACTION NO. 2:08-CV-00079-KS-MTP

BOSTON SCIENTIFIC CORPORATION DEFENDANT

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DEPOSITION OF MICHAEL WEBER, MD

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APPEARANCES NOTED HEREIN

Deposition Taken at the Instance of
the Defendant
In the Offices of Michael Weber, MD
Laurel, Mississippi
On Friday, December 5, 2008
Commencing at 8:30 a.m.

EMM, INC. REPORTING
SHARRA REND, CSR
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STIPULATION

It is hereby stipulated and agreed by and between the parties hereto, through their respective attorneys of record, that this deposition may be taken at the time and place hereinbefore set forth, by SHARRA REND, CSR, court reporter and notary public, pursuant to the rules;

That the formality of reading and signing is specifically waived;

That all objections, except as to the form of the questions and the responsiveness of the answers, are reserved until such time as the deposition, or any part thereof, may be used or sought to be used in evidence.

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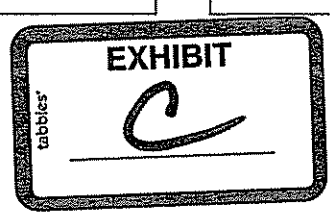

MICHAEL WEBER, MD,
after having first been duly sworn, was examined and testified under oath as follows:
EXAMINATION BY MS. LEDFORD:

Q Good morning, Dr. Weber. Again just for the record my name is Leah Ledford.

MS. LEDFORD: Just let the record reflect that this deposition is being taken pursuant to notice and the Federal Rules of Civil Procedure.

BY MS. LEDFORD:

Q Can you state your full name for the record, please, sir.

A Benjamin, B-E-N-J-A-M-I-N, Michael, M-I-C-H-A-E-L, Weber, W-E-B-E-R.

Q Dr. Weber, we're here today based on a case that was filed against Boston Scientific, who I'm here today representing, by Ms. Jan Hughes, who I understand was a patient of yours.

I just want to be clear that we're not here today trying to point fingers at you for anything. We simply just want to know what happened during the procedure.

So I'm just here today to ask you a series of questions about the procedure itself and the patient's history; and should you not understand

a question I ask, of course please ask me to rephrase it and I'll be happy to do so.

And if you need to take a break or anything like that, we'll be happy to do that too.

That being said, can you just state — give me your address and just kind of your personal information, please, sir.

A You want my home address or the office address?

Q Both, please.

A Okay. Home is 848 North 6th Avenue, Laurel, 39440. The office address is 1008 North 15th Avenue, Laurel, 39440.

Q And what's your date of birth, Dr. Weber?

A 3-12-62.

Q And your social security number.

A 427-27-3218.

Q Okay. And I assume — where are you employed?

A South Central Regional Medical Center.

Q Okay. Are you also employed here with the group?

A The group — all of the physicians in this group are employed by the hospital.

Q Okay. How long have you been employed with South Central?

A Five years, five and a half years.

Q Okay. Just for my purposes can you give me the benefit of your educational background, just kind of a quick rundown in your own words for me.

A Sure. I have a B.S. degree from Millsaps College, Doctor of Medicine from the University of Mississippi Medical Center, residency at University of Mississippi Medical Center in OB/GYN.

Q Okay. Prior to working with South Central where were you employed?

A I've worked — we were in private practice here for 10 years before we sold the practice to the hospital. So I've been in private practice in Laurel for 15 years.

Q Okay. And prior to that time?

A I came straight out of residency.

Q Okay. Great. I know that we had asked you to bring your file today. Other than your medical file of Ms. Hughes, have you reviewed anything else in preparation for your deposition today?

A No.

Q Okay. Did you happen to read the plaintiff's deposition in this case or anything like that?

A I have not.

Q Okay. Have you seen any photographs of Ms. Hughes —

A No.

Q — with regard to the injuries related to this suit?

A No.

Q Okay. When was the last time that you treated Ms. Hughes?

A I have a notation — appears that I saw her last on 11-22-07.

Q Okay. When was the first time, I guess, that you saw Ms. Hughes; and not just related to this lawsuit, but how long has she been a patient of yours, Dr. Weber?

A Let's see. This looks like our new patient form which would have — should be the first time I ever saw her, and it was dated 11-28-1995.

Q So it's safe to say she's been a patient of yours for a good while, then?

A Correct.

Q Did you deliver all of her children?

A Well, I know I took care of her with all of her pregnancies. I'd have to check to see if I actually did the deliveries on all of them.

Q Okay. It's not necessarily important. I don't want you to have to —

A Yeah. Let's see. This is a delivery note from '96. Dr. Stancil actually did her delivery then in '96.

Dr. DeSantis did her delivery in '98. Three, I believe. Let's see the delivery sheet for the last child. But I believe I did it.

No. Actually, this has got Dr. Stancill's name on it. Judging from — these are the labor and delivery summaries that have the physician's signature.

Usually the signature on this summary is who did the delivery, so this one I believe — it doesn't have the date on it. There's a date with her name at the top from '02, and it has Dr. Stancill's name on it.

Q Okay.

A So I would say Dr. Stancill probably did the third delivery.

Q Okay. It's my understanding that she developed a condition following that delivery that

eventually led to the procedure that we're here about today. Would you have treated her following that delivery?

A Yes, I followed her after her deliveries.

Q Okay.

A I cared for her during the pregnancy and then just happened to not be there for the deliveries.

Q I understand. I understand. Do you remember when you first saw Ms. Hughes about the excessive bleeding condition she was suffering from?

A Let's see here. Here's a notation. It's the first I see of any abnormal bleeding. And let me state I don't believe there being a history of a problem before the last child was delivered.

I could be wrong about that, but I don't remember seeing anything before then.

Q Okay. So you don't personally recall her having problems with bleeding prior to that time?

A Well, I should probably look back through and make sure. I don't see anything in the record here before 5-27-04, which is a mention of starting a period on 5-7, and this was dated 5-27, and the complaint was that she was still bleeding on

the episode of this.

"Unsure of medicine changes," I think is how that reads, and we call it breakthrough bleeding, single episode, and started her on Provera. That was the first episode I have of irregular bleeding.

Q Okay. At that time did you know what the cause of the bleeding was?

A No.

Q Okay. When would have been the next time that you saw Ms. Hughes for that condition?

A She phoned back on 6-17 stating that she was still bleeding after finishing the Provera. This is a nurse's note. That she was reassured that this was expected, spotting and light bleeding.

(Witness quietly reads to himself.)

A Watch. If heavy bleeding persists for ten days call back.

Q I'm sorry. Let me interrupt you. You said a drug of Provera. What would that drug have been to treat?

A It's a progesterone. It would have been used to stabilize the endometrium.

Q Okay.

A And then with its withdrawal you have a withdrawal bleeding, so you try to gain control of

the cycle by using that drug.

MR. BLACKWOOD: Excuse me. Off the record for just a minute.

(Off the record.)

BY MS. LEDFORD:

Q Did you finish your answer about the —

A Yeah, I think so. Yeah.

Q Okay.

A The next entry was from that 6-17 phone call.

Q And she had started taking the drug at that time. Is that correct?

A Yes.

Q And I don't think I understood you. How long does the drug take to be effective or to know whether or not it would be effective?

A In an episode like this, once we start that drug we would hope to see some general improvement in the bleeding within four or five days.

We give it — in this case we gave it for 14 days and hopefully to have the bleeding stopped for a period of time. And then when you end the drug, a lot of times you'll expect withdrawal bleeding after that to start a regular cycle again.

Q Okay. And when was the next time that

you had any contact or saw Ms. Hughes?
A Looks like this is October 12 of 2004.
Q Okay. And what was she there seeing you about that day, Doctor?
A The chief complaint was for an annual exam.
Q Okay. And was she still experiencing problems with bleeding?
A Yes.
Q And do you recall what condition she -- or what symptom she told you she had been experiencing on that visit?
A The history of present illness states that she was having some menstrual irregularity, and it also states that she had not had a period since her Provera dose and that she was having mild lower back pain.
Q Would the back pain have been something that was related to this condition, in your opinion?
A Possibly.
Q Okay. What was the diagnosis at that point?
A The impression was a secondary dysmenorrhea, which is pain that is associated with menses.

Q And what treatment options were discussed at this point?
A Medically we started her on a cyclic therapy of the Provera for five days every month for three to four months.
Q Okay. And was she satisfied, I guess, with that treatment plan?
A In December 9 of '04 there was a phone call complaining of bleeding for five weeks, and she was instructed to come in.
Q Okay. And so after that when would have been the next time that you saw Ms. Hughes?
A We saw her on December the 13th of 2004.
Q And what was done at that visit?
A What was done, she had an examination, and it appears that she had an endometrial biopsy and was again put on Provera on -- well, let me back up. Yes, she was started on Provera.
Q I want to make sure I'm understanding the Provera. So it's taken for a span of five days. Is that correct?
A It varies as to how much is given.
Q Okay.
A Sometimes five days, sometimes seven days, sometimes two weeks.

Q Okay. So how long had it been prior to this time that she had taken the Provera?
A I really can't tell from this record when she had taken it prior to the December 13th visit.
Q Okay. But obviously it wasn't working. Is that correct?
A The dose she was on appeared not to be, yes.
Q Okay. This visit she was prescribed the Provera again. And when was the next time that you saw or spoke with Ms. Hughes?
A There's another phone call from January 14 of '05.
Q Okay. And what was that phone call about?
A Stated that the Provera only stopped the bleeding for one week. Now bleeding again. Has refilled for Provera. Can she take, question mark. Yes. Either one or two.
And this is as per H. S., which would be Dr. Stancill. That's a phone call.
Q Okay. And when would have been the next time that she called or came in following that time?
A February 15th she called.

Q Okay.
A And stated she had been bleeding again for two and a half weeks.
Q Doctor, do you know what would have been causing this bleeding?
A Well, let me refer back to her endometrial biopsy to see if we saw anything on it.
Her biopsy did not reveal any abnormalities. So the presumptive diagnosis at this point was what we refer to as dysfunctional uterine bleeding, which typically implies a hormone imbalance that causes the bleeding.
Q I mean, is this a common thing middle-aged women experience or is this abnormal for somebody to be bleeding like this?
A The amount of bleeding that she had demonstrated to this point I think you could say would be considered abnormal.
Q Okay. And going back to the treatment: So she had called in again, and another dose of the medication was given. And when was the next time that she was seen or treated following that time?
A Have we mentioned February 15? I'm not sure where we're at now. But the next entry I believe we were at is February 15, '05, when she

called and said she had been bleeding for two and a half weeks.

And it was recommended that she come in to talk about doing something else, either a D and C versus a hysterectomy is what's noted here.

Q And would that have been you or another doctor in the office?

A To talk to her?

Q Right.

A It would have typically been me as I had been following her.

Q Okay. The two options you just discussed, the D and C and the hysterectomy, can you explain just for the purposes of explanation kind of the definition of both of those procedures in medical terms or in your own words.

A Sure. A D and C, the D stand for dilation, which means to open; C stands for curettage, which I guess typically means to scrape.

So in a D and C it's a surgical mechanism for opening up the cervix enough for an instrument to be passed into the endometrial canal and then that tissue being scraped out down to what's called the basalis layer, the bottommost layer of the endometrium. And a hysterectomy is the procedure of

removing the womb, the uterus.

Q The D and C procedure you're referring to, is that also the ablation procedure that was eventually performed on Ms. Hughes? Is that what the D and C — is that another, I guess, terminology for it?

A No. An endometrial ablation is a separate entity to a D and C. Now, D and C are oftentimes done at the same time ablations are done.

Q Okay.

A But in strict medical sense we would separate the ablation from the D and C.

Q Okay. And when was the next time you saw Ms. Hughes, Dr. Weber?

A February the 16th.

Q And can you tell me what you recall about your visit with Ms. Hughes that day?

A Basically she came in and said she was still having bad bleeding and, you know, it hadn't gotten any better with the therapy that we had been on before.

The reason we had been so persistent with the Provera is that she had had the complications she had after her last child was born. We were nervous about putting her on birth control

pills.

We were at a point now where we felt like we had exhausted most of the medical therapy, that we had tried our best at that and anything else we did probably wasn't going to do any better than what we had done.

And so we moved on to talk about her alternatives, which in this case we talked about the dilatation and curettage, hysterectomy. It appears that I gave her some literature regarding both of those issues and she was going to go home and talk to her family about it and let me know what she wanted to do.

Q Okay. Do you remember if at that visit — do you remember what you discussed specifically about the ablation procedure with Ms. Hughes?

A I don't know that we talked about the ablation at that point.

Q But did you give her a brochure or something on that procedure as well as a hysterectomy? Is that my understanding?

A At that particular visit? I don't believe we talked about ablation at that visit.

Q Okay.

A I don't have any documentation that I did or didn't, but I don't recall talking to her specifically at that point about doing an ablation.

Q So just the D and C and the hysterectomy?

A Yes, based on that note.

Q Okay. And when would have been the next time that you saw Ms. Hughes, Doctor?

A Well, she called back on October the 24th and said she'd been bleeding for four weeks and bled three weeks the month before that. So she was scheduled to come in on 10-26, and it appears that I saw her on 10-26.

Q Okay. Is this of '05?

A I'm sorry. Yes. '05.

Q Okay. So she called on October the 24th?

A Yes. And we saw her on October the 26th.

Q Okay. And what was done at that visit that you recall?

A She had an examination, and she was started again on Provera. She was also given doxycycline and Motrin.

Q You mentioned that the time before when

you had seen Ms. Hughes that y'all had discussed the options. Do you remember what she told you she had decided about doing any procedures at this particular visit in October?

A No.

Q Okay. Is it safe to say she just decided she didn't want to go forward with that type treatment at this time?

A Yeah. I mean, I interpreted that from the fact that it had been February since we saw her, and we discussed that she was going to let us know how she wanted to proceed, and we didn't hear from her again for another eight months.

Q Got you. Okay. So the medication was prescribed. And was that the only treatment that was done on that date?

A In regards to her bleeding, yes. I mean, she had a Pap smear. But, yes.

Q Okay. And when would have been the next time that you saw Ms. Hughes?

A February the 28th of 2006.

Q And what do you recall about your treatment of Ms. Hughes on February 28th of 2006?

A She was in that day to have a repeat Pap smear done. She had had an abnormal Pap smear.

Q Okay.

A She was there to have a repeat Pap smear done.

At that visit she also complained of having no menstrual period for two months and also was complaining of pain and a questionable bulge at her umbilicus, at her belly button; and it was worse when she bent over and strained.

We addressed the Pap smear by repeating her Pap smear, and I referred her to Dr. Ivey, who is a general surgeon, for evaluation of a possible umbilical hernia.

Q Okay. I reviewed the medical records. It's my understanding she eventually did undergo some type of hernia-type procedure. Obviously you wouldn't have performed that. Correct?

A No. Correct.

Q When would have been the next time that you saw Ms. Hughes with regard to the bleeding condition?

A This says August 18 of '06 was another phone call, complaining of bleeding since 7-31-06. Advised of options, medicines versus surgery. Declined surgery. Provera 20 milligrams daily for one week then Provera 10 milligrams daily for 14

days. Call if no help and will need to come in.

Q Okay. And when was the next time that you had any communication with Ms. Hughes?

A 9-19-06.

Q And what was done on that visit?

A Well, my note here says "see Cerner." Cerner is our computerized charting.

Q You don't personally recall?

A Off of this I don't, no. Now, I know that the tag to the end of this says D and C hysteroscopy, endometrial ablation scheduled for 10-25. So apparently that's a conversation that we had that we discussed. The other options including an endometrial ablation.

Q Okay. So that would have been the first time that ablation was discussed with Ms. Hughes that you're aware of?

A As best I can tell, that would be the first time.

Q Okay. Do you recall personally your conversation with Ms. Hughes about that procedure?

A Not in any detail, no.

Q Obviously the procedure was scheduled. Do you know if you discussed with her the -- any potential warnings or adverse events that could occur

as a result of this procedure?

A Well, I don't have any documentation of exactly what we discussed, but in any particular situation where I have an operative patient, I almost always go over -- or I always go over the risks.

I always tell them what the procedure involves, for one thing. This is a new procedure, relatively new procedure, this technique, anyway.

And so I would have explained to her how the procedure was done. For her, she did have some risks with her heart the last time. So I'm almost sure we talked about the fact that just undergoing an anesthetic would be somewhat of a risk.

And with the hysteroscopy procedure there's the risk of perforation of the uterus, and with the hot liquid there's a risk that the liquid could cause some damage if it got outside of the uterus.

Q Are you referring to burns?

A Yes.

Q Do you recall if you discussed those type events with Ms. Hughes?

A I don't recall if I specifically did or not.

Q Prior --

A Now, if we can pull the note from that particular event -- and if -- we may need to take a break and let me go see if that's in the --

Q Why don't we do that now.

(Off the record.)

Q Dr. Weber, we've taken a short break, and have you had an opportunity to pull the computerized note you were referring to prior to our break?

A Yes.

Q Can you explain to me from this note what you discussed with Ms. Hughes on this date?

A Well, there are no specifics to it, but it appeared that we discussed having an endometrial ablation.

Q Do you recall specifically what y'all discussed about the procedure?

A I do not specifically recall what we discussed about it, no.

Q Prior to -- I know earlier you mentioned this being a fairly new procedure. Prior to Ms. Hughes, do you know how many of these procedures you might have performed?

A I can't tell you specifically, but I'm guessing she was the fifth or sixth of the

endometrial ablations, yeah.

Q Okay. Would they all have been using the same product, the same machine?

A Let me kind of clarify that.

Q Okay.

A When I first moved to Laurel we did something called endometrial ablation that used something called a roller ball, and we abandoned that several years after I moved here.

So we have not done ablations until the newer procedures, as the hot thermal ablation, had come about. So the answer to I think what you're asking is yes, that's the only technique we had been using at that point.

Q Okay. I mean, would all of these procedures obviously been performed at South Central?

A Yes, and they would have all been the hydrothermal ablation at this point.

Q Okay. Would they all have been using the same machine?

A I don't know the answer to that.

Q Okay. Do you know anything about the history of that particular machine that was used for Ms. Hughes's procedure?

A This specific machine?

Q Uh-huh (affirmative). The Boston Scientific Hydrothermal --

A I don't know anything about it specifically, no.

Q Okay. You mentioned doing maybe five or six of these procedures prior to Ms. Hughes. Do you know if they were all using these same type machine?

A The Boston Scientific same type machine?

Q (Nodded head affirmatively.)

A As far as I know they were all using the same machine, but I don't know --

Q -- if the hospital had more than one of the machines?

A Right. I don't know if they were interchanged or changed out or whatever. I don't know that.

Q Okay. I understand. Thank you for clarifying.

But all the times that you performed this procedure, even if it wasn't the same exact one, it was all using the Boston Scientific?

A Yes, yes, yes.

Q Did you have any training for using that device? Were you ever trained to use that machine by anybody with the hospital, by anybody from Boston

Scientific?

A From Boston Scientific, yes.

Q When would that have been?

A The first several that we did -- and my partner also does them, so we attended the procedures when we started it. So the Boston Scientific folks are the folks that taught us how to do this machine.

Q Okay. Did you attend like a class, for lack of a better term, or, I mean, did they come to the hospital? Did they --

A They came to the hospital to do it, yeah.

Q Okay. What type training did that entail? How long of a training period would that have been, to the best of your recollection?

A Well, for us the training period is not that extensive, because all we're really doing -- structurally we're performing a hysteroscopy, which we've done since I've been in practice.

The only difference in a hysteroscopy and the ablation procedure using this technique is that the fluid that you use to distend the uterus is sent to a warmer and then back into the uterine cavity.

So the amount of training -- I don't

know. Maybe an hour or two. But I don't have any specific recollection of the training process itself.

Q Okay. That was my next question. Do you recall who from Boston Scientific you met with?

A I don't remember his name, but there was a specific person, and I'm sure we can identify.

Q Okay. And do you remember — other than him showing you how to use the machine, do you remember him discussing any warnings or adverse events that were side effects of this procedure?

A Well, yeah. You know, the biggest concern doing hysteroscopy is perforation of the uterus. And the biggest concern using a heated distention medium that they use for this procedure was the possibility of that fluid leaking on to structures that didn't need to be heated.

And with a perforation you're worried about internal injury to the bowel or the bladder, and then you're worried about cervical leakage that could cause a burn in the vagina or on the perineum.

And I think the bulk of our training dealt with making sure that those seals were correct and that we didn't overdilate the uterus and things of that nature.

Q Okay.

A And their representative was also present for I think — and I — again I'm not positive about this. I think Jan was only the second one that we had done that he hadn't attended with us.

Q Okay.

A So the representative was there at the beginning for all of our procedures to make sure that we had a full understanding of the procedure and that we were doing it correctly.

And then when we felt comfortable and he felt comfortable he stopped attending all of the procedures.

Q Okay.

A And I don't believe he was present for Jan's procedure.

Q Other than the training you received, have you done any further training with regard to using this machine?

Well, let me start there. Have you had any further training, other than somebody coming to the hospital and then also sitting in a few procedures with you?

A No.

Q Okay. Would you have done any independent research on the Internet or through

journals or anything like that on this procedure?

A Well, Boston Scientific provided some — I believe a video and also a manual that went along with it, and I remember going through those.

Q Okay. Were you also given any type brochure from Boston Scientific on, like, handouts to patients?

A Yeah.

Q Okay. Do you remember if you gave that to Ms. Hughes?

A I don't.

Q Okay. And then you mentioned a manual of some type and a video.

A Uh-huh (affirmative).

Q Other than those two items do you remember being given anything from Boston Scientific about the procedure?

A No.

Q Okay. Just for the sake of us who aren't doctors, can you just in your own words describe the ablation procedure.

And I know you briefly did that a few minutes ago, but just the procedure itself and kind of what it's designed to do.

A Okay. Well, the procedure itself — to

ablate something, I guess, since it essentially means to get rid of it, to — in this case a heated liquid is used to thermally destroy the lining of the uterus itself.

That fluid is circulated through an instrument called a hysteroscope that goes into the uterine cavity, circulates around, and then exits back through the scope.

It is heated to a certain temperature, and that temperature is hot enough to cause the ablation of that tissue. That's it in a nutshell.

Q Okay. And there's — my understanding is there's some type of warmup phase and then a cool-down phase. Is that correct?

A Right.

Q How many minutes is the warmup phase?

A I think it's two minutes.

Q And the procedure itself, do you know how long?

A It was ten minutes.

Q And then the cool-down phase?

A I don't remember. It's a couple of minutes.

Q Couple of minutes?

A And it may vary. I don't remember now.

I think it's based on the temperature that reads out of the fluid.

Q Okay. And your role as a doctor in using the machine to perform this procedure, what would your role be?

A My role in this is to actually perform the procedure itself.

My role from the beginning of the procedure is to position the patient, insert the hysteroscope into the endometrial canal.

A diagnostic hysteroscopy is performed; that is, basically you put the fiberoptic light, the hysteroscope, into the uterus to look around, to make sure that there wouldn't be some reason that you might not want to perform the procedure, and to make sure that the hysteroscope is positioned at the right place, and then to monitor the ablation as it's taking place.

Q I personally have not seen one of these machines other than looking on the Internet and through handouts.

A Uh-huh (affirmative).

Q Are you pushing buttons on a machine to work it, to start the different phases, and then are you watching the machine? How does that work?

A Well, the machine is not sterile. So somebody else — the circulating technician in the operating room is actually the person that pushes the buttons.

Q Okay.

A But what we do is — you asking what my personal — what my responsibility is in this?

Q Yes, sir.

A Okay. This is a procedure that's done during visualization, so you actually — you have a video image. We have a TV screen and we're watching what's going on.

My job or my responsibility during that is kind of twofold or threefold. We're watching the screen. We're watching what's going on in the endometrial canal.

We typically have our eye on the cervix to make sure we don't see fluid coming out of the cervix; and then we also have an eye on this cylinder, this graduated cylinder, which is the thing that measured — it was their safety — it's the safety device for the machine that is designed to cut the machine off if it detects a drop in, I think, ten ccs of fluid, which means there could be a leak somewhere.

Now, we have — everybody in the room is essentially watching those three elements.

Q Okay.

A But you're right. There's buttons that are pushed. It's a very straightforward machine. It tells you exactly what the next step is, when to do it. If there's something wrong, it actually troubleshoots. It's a very straightforward machine.

Q Are warnings or — you mentioned like a fluid loss or things like that. But does all that just kind of flash up I guess on the machine itself?

A Yes. There's a digital readout on the machine itself.

Q Okay. Would you have had any role in ordering this machine for the hospital or requesting it or anything like that?

A I did not have a role in ordering it. But we liked doing the ablations; so I guess in terms of requesting something, we asked that we be allowed to do that procedure at the hospital. Yeah.

Q Okay. And then the hospital would have —

A — gone through whatever steps they go through to get it —

Q Okay.

A — which I'm not familiar with.

Q Okay. Do you remember at what time period, when the hospital obtained the machine to do these procedures? Do you remember what year?

A As opposed to having somebody from Boston loan us one to do them or —

Q Well, that's a good question. Did Boston Scientific loan y'all a machine?

A I'm assuming that we used a machine on a trial basis to see if we wanted to do the procedure. But again I'm speaking from something I don't know about.

All I know is we were approached about doing ablations. We voiced an interest in that. There was a machine.

Q Okay.

A So where it came from, I don't know.

Q Okay. Do you remember what year that would have been?

A What year it came?

Q Right. What year y'all first started doing these.

A I really don't.

Q Okay.

A We had probably — this was in '06.

Probably in '05 or early '06, I guess.
Q Okay.
A And I'm sure there's someone at the hospital that can tell us very specifically when we started.
Q I know we talked about a handout that you said was given from Boston Scientific, but is it my understanding that you don't know if you gave that to Ms. Hughes or not?
A Right.
Q Okay. And your records indicate that y'all discussed the procedure and the risks and everything, but you don't recall what y'all discussed. Is that correct?
MR. BLACKWOOD: Object to the form of the question.
MR. WILLIAMSON: You can go ahead and answer.
BY MS. LEDFORD:
Q You can answer.
A I don't have any specific documentation of that. My preoperative note again talks about the fact we discussed the risks of the procedure; but in terms of the specifics, I don't have any documentation at hand today that shows that.

Q Okay. And I understand. I know you see a lot of patients. I just wanted to make sure I was clear.
The procedure itself, it's my understanding, occurred on October the 25th of 2006. Without looking at your notes — and I'm not — but do you personally recall anything about it, or is all that you recall just from your memory of reviewing the notes?
A No. I mean, I remember some things about it. It was an unusual day, so I do remember some of it.
Q Okay. What do you remember — I guess just — you wouldn't have been involved in the preparation for the procedure as far as prepping Ms. Hughes, would you?
A Can you be more specific about that?
Q I guess — on that day when was the first time that you saw Ms. Hughes?
A I usually speak to the patient in the holding area, in the preoperative anesthesia area, before they've had any sedation or anything. I always go around and speak to the patient, ask them if they have any questions, and then the patient is taken to the operating room.

Q Okay. And so the next time you would have seen her was —
A In the OR —
Q Okay.
A — as she goes to sleep.
I'm always in the room when the patient is induced, when their anesthesia is induced.
Q Okay. What happened, just in your own words kind of what you remember about what happened?
A Well, essentially what I remember is we went in to do the procedure, Jan got put to sleep, we prepped her, put her up in the stirrups as always. We did the procedure as we always had done it.
And just basically eight minutes into the procedure, I mean, it was almost all simultaneous. We hear a beep, I'm staring at the cervix, I start to see some fluid leak out, and the machine, you know, gives us the warning that there's been a breach.
And so we stopped the procedure. You know, it automatically shuts off. So we held still. We're still looking at it on the hysteroscope. Nothing in the uterus looks any different, but we do see this — you know, we see a small amount of fluid coming out of the cervix into the vagina.

When we get the clear that the fluid has cooled down we take the scope out, and that's when we noticed that she'd been scalded where that fluid had reached.
And so we applied some — I think some medicine in the OR, even put some Silvadene on it. She was awakened from anesthesia, taken to the recovery room.
Q Let me back up. You mentioned a breach. What do you mean by there was a breach?
A You know, an escape, a leak.
Q Okay. Do you know what caused the leak?
A I do not.
Q And you said it all happened simultaneously, I believe is what you said, that you saw a leak and the alarm sounded.
A (Nodded head affirmatively).
Q Do you know what the machine was designed to do if there was the chance of the leak?
A Well, yeah. It's — you know, it's a closed system, which means it's supposed to keep up with the amount of fluid. There's no fluid being dispersed.
An open system, the fluid goes in and it just drains out, you know, into a bag. This is a

closed system, which means the fluid that goes in also goes back. It's an enclosed system.

There's a part of that system in the Boston Scientific machine that keeps — it's a graduated cylinder basically that keeps up with fluid changes; and if it loses ten ccs or more, an alarm sounds. And when it loses ten ccs, the ablation automatically shuts off. I think that's what you're asking.

Q Yes. Do you recall who all was present during this procedure, Doctor?

A By name, no. It will be on an OR record somewhere, but I don't have those records.

There would be a circulating tech, there would be an anesthesia person, there would be my surgery scrub tech. So there were at least four of us in the room, and I don't remember if there were any other people there.

Q And you don't recall anybody by —

A I don't recall anybody specifically by name, no.

Q Okay.

A I mean — and I don't think my note mentions anybody by name. The surgical note, the hospital would have that, though, the OR record that

they keep.

Q You mentioned earlier that leaks and burns were discussed as adverse events that could occur with this procedure. Is that correct?

MR. BLACKWOOD: Object to the form of the question.

BY MS. LEDFORD:

Q You can answer.

A I believe that we would have discussed that, yes. That's a key element to this procedure. I mean, that's the worry that you would have with this particular procedure.

Q Was it discussed what would cause those leaks? Do you recall?

A No.

Q And you don't know what caused Ms. Hughes's leak. Is that correct?

A That's correct.

Q Would you categorize this as what was described to you as a potential risk of the procedure?

A Yeah.

Q Did the machine in your — the way you had been trained to use it and the way it was described to you what would occur should a leak

unfortunately happen, did the machine shut down the way it was described to you that it should?

A The machine did shut down, yes.

Q And the alarm sounded?

A And the alarm did go off, yes.

Q Okay. Prior to this incident with Ms. Hughes, are you aware of any other similar type incidents that might have occurred with this procedure?

A At our hospital or just in general?

Q At this hospital.

A Not at our hospital, no.

Q Okay. Prior to this incident occurring had you discussed this procedure with any other doctors within your hospital or not?

A I'm sorry. Could you repeat that question.

Q Sure. It was a bad question.

Prior to doing the ablation on Ms. Hughes, did you discuss with any doctors at this hospital the procedure?

A Dr. Stancill and I have had conversations about it because he's been performing them as well.

Q Okay. Did y'all discuss the leaks that

can occur? Did y'all discuss that at all?

A I don't really have any recollection as to the specifics of that. I just remember we spoke about it.

Q Had you ever discussed that with any other doctors at other hospitals who had had a similar type experience —

A No.

Q — occur?

Okay. Following Ms. Hughes's procedure did you discuss this leak with anybody, any other doctors?

A I probably discussed it with Dr. Stancill, yeah. But I don't specifically remember having a conversation with him about it, mainly because we didn't do it again after she had that injury.

Q Okay. And that's what —

A And I think that was it. We just — I discussed to him that I had had a problem just as a heads-up, "I had a problem. We don't really know what happened, but here it is."

Q Okay. So following Ms. Hughes's procedure y'all no longer did the ablations?

A I did not.

Q Okay.
A I did not do the Boston Scientific ablations. We still do ablations.
Q Okay. So you have not used the Boston Scientific machine since this --
A Since her incident, yes.
Q Do you know what was done with that exact machine that you used during her procedure?
A No.
Q Do you know if it was tested to see if --
A I have no -- I reported it. And any incident like that was reported to the OR staff, and to the best of my knowledge they have procedures and protocols for dealing with incidences like that.
I believe Boston Scientific was notified about it, and what happened after that I have no idea.
Q Okay. So you don't know or you haven't been made aware of anybody running any tests on it or anything like that?
A No, no.
Q Okay. Following this -- well, let me ask you this: Did you discuss or have you been made aware from other doctors about a similar leak

occurring even at other hospitals, just any doctor? Have you discussed this?
A Well, I mean, if you read the literature that associates the product itself -- you know studies are done on these things -- you're aware that leaks can occur.
Q Okay. Are you talking about --
A But not necessarily specific to the kind of leak we experienced here, I'm not.
But just talking about -- I mean, the product manual itself speaks of leakage of fluid from the cervix and leakage of the fluid during perforation.
Q Okay. I'm sorry. You said something a second ago about not the particular leak that occurred here. I'm just -- what do you mean?
A Well, a cervical leak three-fourths of the way through the procedure, I guess is what I'm trying to say.
Q Okay.
A I guess I should better phrase that by saying, specifically I'm not aware of any particular manner that a leak occurred, just that leaks have occurred.
Q Okay. But that's mainly just from the

materials and manuals and things?
A Yeah, just from a scientific study.
Q Right.
A Not from personal knowledge of anything.
Q Following the incident did you -- on that very day did you speak with Mr. or Ms. Hughes about what happened?
A Yes.
Q Do you recall those conversations?
A I mean, I just went and told them that we had a problem, that some fluid leaked out of the cervix into her vagina, and that she had what appeared to be second-degree burns from it.
Q Did you tell her that the machine malfunctioned in any way?
A I don't recall telling her that anything had malfunctioned but just something had happened.
Q Would it have just been more like a problem or a complication?
A I saw it as a complication. To be honest with you, to this moment I still don't know exactly what happened. So I've chosen not to try to lay blame somewhere because I don't know what happened.
Q Okay. You mentioned putting some cream

on that day. What did -- and you said a scald, I believe. What did you -- what were her injuries that you perceived on the day of the incident after the leak occurred?
A This is straight from the record. There was a three-by-two-centimeter scald area on the outer perineal body, which is basically the skin outside of the vagina, and a small area of similar size inside the vaginal introitus. So there was a spot inside the vagina and then a spot on the outside.
Q Will you --
A At some point I believe I even attempted to draw a picture of it.
Q Okay. Were you able to determine the severity of the burn?
A It appeared to be a second-degree burn. It was blistered. It did not appear to be worse than that. There was no necrosis noted or anything.
Q Okay. And what treatment did you provide Ms. Hughes on that day?
A This says Premarin cream was applied to the burn areas. I would love to go back and recheck the operative note -- I mean the OR record for that to see if we didn't apply Silvadene, but Premarin could have been what we put on it as well, which is

an estrogen cream.

Q Okay. Was that the only treatment that was given that was needed for Ms. Hughes on that date?

A That's all, yeah.

Q Okay. And the next time you saw her was the next day at your office. Is that correct?

A Let's see. I have a note of 10-26-06 that we saw her, yes. It would be the day after.

Q And obviously did you discuss what happened again with Ms. Hughes that you recall?

A Yeah. I mean, she had been under an anesthetic before, so I think it was a little clearer time to just go over it.

Q Okay.

A I don't have the specifics charted as to what we talked about, but I felt sure we did.

Q Did you examine Ms. Hughes on that day?

A Yes.

Q And was there any change that you could tell in her — in the burns?

A Two-to-three-centimeter area on the perineum and a small intravaginal area — I actually put one to two centimeter here.

There was no significant change at that

point, one day later, no.

Q Okay. And what was the treatment plan at that point?

A Silvadene cream.

Q Would that have been something that you gave Ms. Hughes or something that she would have had to have gotten filled?

A It would have been a prescription.

Q A prescription. Okay. And following that was any other treatment given to Ms. Hughes on that day?

A That day, no. We planned — no.

Q Okay. And when was the next time that you saw Ms. Hughes?

A On the 30th.

Q So a couple of days later. And what — did you examine Ms. Hughes on that day?

A Yes.

Q And what was — was there any change in the burns, in her condition?

A She was complaining of a vaginal discharge, which I had noted, which more than likely was coming from the ablation itself, which was normal.

On the examination I noted that she had

some surrounding erythema, which would just be some redness around the edges of the burns; but there were no signs or symptoms of infection. And I put "Looks okay. Continue the Silvadene and follow up in three days."

Q And did Ms. Hughes describe her pain to you?

And let me back up. Following the incident was Ms. Hughes in pain that she — did she communicate to you that she was in pain from the burns?

A On the first visit or on any visit?

Q Backing up. Immediately following the procedure do you remember if Ms. Hughes was in —

A Well, immediately following the procedure she would have been in pain from the procedure even if she hadn't had a burn.

Q Okay.

A So it would be hard to delineate one from the other.

Q Do you recall her telling you that she was in pain from the burns, that the burns were causing her discomfort at that point?

A At which visit?

Q On the day following the —

A The day following the procedure?

I didn't make any notation of it, but she could have. I just didn't note that.

Q Okay. And I believe we're on the 30th, the date is what we were discussing.

A Right.

Q Other than the cream and the examination was any other treatment provided for Ms. Hughes on that day?

A No. We're just to follow her up. And this was basically being treated like a burn. So we, you know, put the medicine on it and decided to give it time. And we kept an observation to make sure it wasn't going to get infected.

Q Okay. Did Ms. Hughes come in again following that date?

A She came in on — let me make sure these aren't out of order.

I've got a whole set of notes here that look like I've got the year wrong on them. No. Maybe not. 12-5-06 looks like the next time we saw her.

Q So 10-30 to 12-5-06. Okay.

A Can I stop just a minute?

Q Sure. Do you want to take a break?

A Yeah. Let me go off the record just for a minute.

(Off the record.)

Q Dr. Weber, we've been on a break; and have you had a chance to go back and see if you did indeed see Ms. Hughes at the Ellisville clinic?

A Yes. It appeared that we saw her on 11-2-06.

Q Okay. So that would have been following the October 30th visit.

A Right.

Q The next time you would have seen her would have been on November 2nd.

A Right. And that was what was scheduled to follow up in three days.

Q Okay. And can you tell what treatment was provided to Ms. Hughes on that date?

A I cannot.

Q Okay. When would have been, after that visit, the next time that you saw Ms. Hughes?

A 11-8.

Q '06?

A '06, not '07. That's what she was pulling up here was those notes, 11-8, 11-15, 11-22, and 12-5.

This is just a printout of the business record of when she was here, so just trying to make sure those dates are not -- they are -- they just have the year wrong on them.

Q And we'll get through those, but just for the sake of clarity for the record, it's my understanding that you have stated your medical records were dated '07, but it should have been --

A '06.

Q -- '06?

A For those three entries, yes.

Q That would make a lot more sense.

A Yes.

Q Okay.

A And I got them to pull up her check-ins there on computer here, and those do coincide with '06, not '07.

Q Okay. So the next time after the 2nd that you saw Ms. Hughes was back here in the Laurel office?

A Correct. The rest of the visits were in Laurel.

Q Okay. And what date was that?

A 11-8.

Q And what -- did you examine Ms. Hughes?

A Yes.

Q And what was -- at this point how were the wounds healing? Do you recall or can you tell from reviewing your chart?

A The examination states the burns are healing well and they are starting to granulate.

Q Can you just --

A It means it's healing.

Q Okay.

A Granulation is a form of -- primary healing is if a cut is made and the two skin edges are proximated together, they will heal with the skin over it.

A secondary form of healing is called granulation, which is where an open wound will heal. It's just a repair process. That would be a sign that it's healing properly.

Q Okay. And is she still using the Silvadene cream you were talking about earlier?

A It doesn't state here if she's using it or not. I have to assume that she's still using it for that.

Q Okay.

A There's no dictation that we've changed her treatment at all.

Q Okay. Other than that cream were any other medications prescribed --

A Not that I can tell.

Q -- for healing or for pain? Do you know? And --

A Yeah.

Q -- I'm kind of backtracking here.

A Right.

Q Do you know if any pain medication was prescribed?

A Well, I prescribed her pain medicine with the initial procedure.

Q Would she have required pain medication for the procedure itself even without complications?

A Usually for a day or two, yes.

Q Okay. What is a typical recovery period for the procedure itself, again without complications?

A It varies from patient to patient. But my experience so far has been most of the patients will be uncomfortable enough to require pain medicine for usually one to two days, oftentimes as long as five or six days; and that they will have a perceived vaginal discharge anywhere from a few days even up to ten days to two weeks.

But their comfort level in terms of being able to carry on their day-to-day activities is almost always back to normal within a few days.

Q Okay. The standard again without complications: When after the procedure occurs would be the next time that you would see a patient?

A I normally see everybody back in a week.

Q And if there aren't any problems, when would be the next time you would see a patient after the ablation, just their next —

A It depends. Yeah. Their next annual checkup.

Q Okay. Going back to the follow-up treatment of Ms. Hughes.

A Yes.

Q I can't remember what date we were on now, but —

A The 8th, I believe.

Q November the 8th. Do you recall what treatment was provided for Ms. Hughes on this date?

A There's no specific treatment change other than to follow up in a week. So, like I said, the assumption is to continue doing what she's been doing.

Q Okay. And when — the next time you saw

Ms. Hughes was —

A — was 11-15-06.

Q And was everything still healing properly?

A The notes basically say, Doing well, continues to improve, improving, plan one week — follow up in one week.

Q Okay. Are there any description as to, I mean, I guess the wounds at this point? Do you recall if — I mean, any bleeding or any abnormalities or any other type issues associated with injuries?

A No changes for the worse.

Q Okay.

A No.

Q Okay. And the next time you saw Ms. Hughes was?

A 11-22.

Q Okay. And?

A Continues to improve, area at perineum almost completely healed, vaginal area healed; impression: Continues to improve. Follow up two weeks, continue management. Just basically keep doing what we've been doing.

Q Okay. And you said almost healed. Do

you recall if these areas left a scar of any sort?

A I don't recall, but they probably did, yeah.

Q Okay. And the next — when was the next time you saw her?

A The last entry I have is 12-5-06.

Q Okay. And what was done?

A Complains of lower back pain, cramps, and some spotting started last week. Took a pain pill last week and feeling better. Started again, last one to two days.

Her back examination, she was nontender — the uterus was nontender and the perineum appeared to be healing well. I felt that she was stable. I gave her an anti-inflammatory called Ansed, which was prescribed for 100 milligrams three times a day for three days.

And I don't even have the plan for what her further follow-up would have been.

Q Okay. Do you associate the back pain to the procedure itself or from the leaking or do you know?

A Oh, I didn't associate it with one or the other, no.

Q Okay. So —

A I mean, she had had some spotting too. So in a lot of women when they have their period or when they go through the motion of having their period will have back pain as well.

Q Okay. So you're not sure what it was caused from, then. Is that —

A No.

Q Was that the last time that you saw Ms. Hughes?

A That's the last record I have of seeing her, yes.

Q Okay. So you have not seen Ms. Hughes since that date?

A I have no record of seeing her since then, no.

Q Have you seen any medical records or been made aware of any conditions or symptoms she might have continued to have since that time?

A No.

Q Do you recall one of the risks being described to you of the ablation procedure is that it might not be effective in treating the condition, the bleeding condition? Is that a known risk?

A Yes.

Q Okay. Do you recall if you communicated

that to Ms. Hughes?

A Yeah. I mean, again I don't have a specific record to that effect; but it would have been — in discussing this procedure, one of the first things we talked about is the fact that the procedure — and I usually would say, you know — and what I usually told folks, and this is based on the literature that I had read about it, that there was almost a 50 percent chance that she would never have another menstrual period again, a not-quite 50 percent chance that she may experience a small amount of bleeding but it would not be an unmanageable amount as she had been experiencing before, and probably a less than 5 percent chance that the procedure itself would have done little good at all and she would still require another procedure of some sort after that.

Q Okay. And you said that you normally told folks about — are you just talking about that was generally what you told every patient?

A Yes. That's generally what my counseling involves when I talk to patients about ablation.

Q Okay. Do you know kind of by the same token how you describe other risks? We've talked

about the leakage and the burn.

A Yeah. I didn't quote any kind of a number or anything like that other than to say that in general it's a — not a very risky procedure in terms of frequency of incidents like that happening.

We've never had a hysteroscopic or an ablation complication prior to this.

Q But generally that was just what you would describe to other patients?

A That would be a general description, yes.

Q You've mentioned a couple of times the hystrascopy (sic).

A Hysteroscopy, uh-huh (affirmative).

Q Hysteroscopy. What is that procedure?

A Well, a hysteroscopy itself involves placing a hysteroscope, which is a fiber-optic light, through the cervical canal into the uterine cavity in order to visualize the inside of the uterus.

Q Okay. Would that be part of the ablation procedure?

A It is part of the ablation procedure.

Q Okay. That's — so it's mainly just exploratory?

A It's exploratory, right. And it's done

initially to, A, make sure you are in the uterus and not somewhere else, B, to make sure that there are no uterine abnormalities that might prevent you from wanting to proceed with the ablation.

Q Okay. That makes sense.

A It also in this particular — in the Boston Scientific method of doing the ablation the hysteroscopy is also performed while you're doing the ablation.

So you actually can watch the blanching or you can watch the thermal effects of the procedure while it's actually happening, which is different than some of the other procedures.

Q Okay. You mentioned earlier that somebody approached you, I believe you said, about the ablation procedure. Do you know who that would have been?

A I don't.

Q Would it have been like a salesperson from Boston Scientific?

A It would have either been a salesperson or my partner.

Q Okay. All right. As far as the complication that occurred in Ms. Hughes's procedure — I just want to make sure I'm

understanding correctly. Is it your testimony that you don't know what caused the leak?

A That's correct.

Q And are you — is it your opinion in any way that the machine malfunctioned in causing this leak?

A I don't know if it did or it didn't.

Q Okay.

MS. LEDFORD: Can we take a break for just a few minutes?

(Off the record.)

BY MS. LEDFORD:

Q Dr. Weber, you mentioned that you stopped doing this procedure following this incident with Ms. Hughes. Can you tell me why you stopped doing it?

A Well, to find out if there was some particular reason, you know. Were we putting patients at risk perhaps that we didn't know about, to evaluate our equipment, to make sure — you know, to be honest with you, it doesn't take but one of these sorts of problems to make you think about doing something else.

There were alternatives that were being, you know, brought forth. I think some of the other

OBs in town had mentioned doing alternative procedures.

So at that point we said, Let's stop and evaluate where we are. Is this the right thing to be doing? Is there a potential problem with it? Is this just one of those, you know -- anybody that performs surgery realizes that complications can happen.

And was this one of those things or is it -- do we just need to evaluate it and see if we need to do something differently.

Q And was that evaluation process that you just described, I mean, was that done? You mentioned you didn't know if the machine was tested.

A Yeah. I mean, I left that up to the surgery department to have -- to let, you know, Boston Scientific -- to let our guy know that we had had a problem and did something need to be looked at.

And then just from our own personal standpoint we just took a giant step back and said, Look, you know, we've had this happen to us. There is another procedure or, you know, there are other procedures out there. Is there potentially a better way of doing it?

Q Okay. Do you know -- did the hospital

and all the other doctors, did everybody stop doing the procedure, the ablation procedure after this incident?

A I'm not positive, but I believe that Dr. Stancill and I were the only two doing the Boston Scientific procedure at the time. I believe the other physicians who were doing ablations had changed to the Novasure product.

Q Okay.

A So we were the only ones doing it at that time. The others had changed to another product.

Q Okay. And both of y'all stopped using Boston Scientific. Is that correct?

A At that point, yes.

I should say I believe we both did. I don't believe we did any more procedures with that technique after Jan's procedure. Anybody. I don't think anybody did, but I know specifically for myself I didn't.

Q Did y'all decide that this procedure was too risky? Is that my understanding? Is that why y'all decided to stop using it?

A "Y'all" being?

Q You and your colleague.

A Me and my partner --

Q Right.

A -- or everybody in the department?

Q Well, I guess whoever else was doing this procedure, if y'all decided -- I'm being very southern by using "y'all."

A That's okay. I just want to make sure the "y'all" is -- does "y'all" mean me and Dr. Stancill, just the two of us, or the whole department, because there are other people in the department that use the Novasure.

Q Right.

A I believe they switched to it just because their perception was that it was a little easier. It didn't take as long.

Q Okay.

A It's a two-minute procedure instead of a ten-minute procedure.

Q It's designed to do the same thing?

A It's an endometrial ablation device, but it does it different. And up until I had the issue with Jan, I actually -- I liked some of the components of the Boston Scientific over the other.

Each had its pros and each had its cons.

Q I understand. I guess --

A But to answer your question, actually, Dr. Stancill and I, after this happened, did decide that we would look at the other product and probably stop using this one.

Q And is that what happened?

A Yes.

Q Okay. So y'all continued to do the ablation just using another --

A Yes.

Q -- product?

A Right.

Q Okay. And let me back up and kind of change gears too.

The follow-up visits that you had with Ms. Hughes, did you -- I know your notes indicated the healing process of the burns.

Do you recall any conversations you might have had with Ms. Hughes during that time period about her pain level, any pain she experienced associated with these burns, if it was affecting her daily life?

A You know, since there's nothing charted, I can't say specifically yes or no to that question.

My feeling is that were there some inordinate problem, you know, some increasing problem

or some persistence or something, that we would have noted that and, you know, noted some prescribed treatment for that as opposed to the fact that what it appears we were doing is just looking at —

Now, does that mean she was in no pain at all? I can't say that because she had a burn. But for it to be something have changed or something any different than before, I don't specifically recall having that conversation with her.

Q Okay. The last visit in December where you saw Ms. Hughes —

A Yeah.

Q — were the burns healed completely at that point? Do you know?

A It says "healing well," so I can't say for sure that that's 100 percent completely healed.

Q Okay.

A It says healing, so I would have to say at that point they were not completely healed.

Q And you wouldn't be able, I guess, to offer any testimony about when precisely they completely healed and any residual scarring that might have continued?

A After December the 5th I have only seen Jan in public, and we have not spoken about this at

all.

Q Okay. The other procedure that you were talking about, and I assume — do you still use that procedure?

A Novasure?

Q Right.

A Yes.

Q You mentioned that it was different and shorter. It's designed to do the same thing. Is that correct?

A Correct.

Q What does that product — I guess just in your own words describe what it does and how it works.

A Well, whereas the hydrothermal ablation circulated a liquid that was heated in the endometrial canal to provide that thermal injury to the endometrium, the Novasure is an actual physical device that fits into the uterine cavity; and it opens — it's shaped like the inside of the uterine cavity and a bipolar electric current flows through that. So it's cauterized using electric current.

Q It takes two minutes?

A Two minutes. Not more than two minutes. Actually, that particular device, the time limit is

based on resistance, which is read through the instrument.

And when the resistance gets to be a certain point, the ablation ceases. So it's never longer than two minutes.

Q Okay. And it is removing the —

A It's doing the same thing. It's destroying or ablating the endometrium.

Q Okay. Is the patient asleep during that procedure, I assume?

A They are, yes.

For the way we do it, the patient is asleep. I'm under the understanding that there are some places that try to do this with conscious sedation, but I'm not ready to go there with patients yet, so...

Q Say the name of it again for me, the Novak?

A Novasure, N-O-V-A-S-U-R-E.

Q Thank you. Probably for her that helped her.

Does it have — I guess what are the risks associated with that procedure?

A Basically the same as with the hydrothermal ablation in terms of perforation of the

uterus during the dilation and hysteroscopic portions of it and thermal injury as well.

Q Is there a risk that it won't be effective?

A There is a risk that it will not be effective; and, again, I usually quote approximately the same numbers as I quoted for the other.

MS. LEDFORD: Okay. I don't think I have any other questions at this point.

Jim, do you?

MR. BLACKWOOD: I do.

EXAMINATION BY MR. BLACKWOOD:

Q Dr. Weber, my name is Jim Blackwood. I represent Jan Hughes.

Earlier in your testimony you discussed risks associated with using the HTA, one of which is the risk of burning.

A Yes.

Q Correct? And the risk of burning, I take it, was directly related to there being a risk of some type of leak during the procedure. Correct?

A Yes. And there's also apparently been — this is just through reading their literature — that a potential problem is if the tubing that the fluids pass through was draped across

the patient, across an appendage or something, there could be a thermal injury that way as well.

So we were always instructed never to lay the tubing that the fluids pass through on the patient. They were always supposed to be free. But those would be the two ways of a thermal injury.

Q Okay. Well, I want to talk about leaks for just a minute. What are the possible ways that a leak can occur during one of these procedures?

A Well, essentially in my mind the two most common ways a leak could take place is if there's a perforation of the uterus, which means there's an injury so that a hole is basically poked through the wall of the uterus and the fluid, as it's circulating, could leak out.

In that particular case, depending where the perforation is, the fluid can leak into the abdominal cavity. I guess if it were anterior, it could potentially leak all the way into the bladder. You could have an injury there.

And then the other way that a leak could happen is if it leaked around the cervix itself where the scope is being put through.

Q No perforation occurred to the uterus in Ms. Jan's case. Is that correct?

A Not that we're aware of. Okay.

Q Okay. Now I want to talk about leaks around the uterus. What can cause a leak around the uterus with this device?

A Around the cervix?

Q I'm sorry. Around the cervix, yes.

A Well, if the cervical canal is too large for the instrument and there's not a seal around it, that could potentially be a problem.

If the device were to, I suppose, be placed in the wrong position, that could potentially lead to a leak. And kind of owing to that, during the procedure itself if the device were moved into an inappropriate position during the procedure you could get a leak.

Q Okay.

A And I suppose movement itself, even if the device were in place, theoretically could be accountable for a leak as well.

Q Okay. Let's talk about the positioning of the hysteroscope. Did you place the hysteroscope properly or as instructed by Boston Scientific?

A Yeah, we did. We put the scope in — the sheath for the scope is a special sheath that comes with that particular instrument, and the proper

placement is just inside the endocervical canal.

And you can visualize that with — that's why we do the hysteroscope is to make sure visually that we're in the proper place.

We used two tenaculums on the cervix to make sure that — basically a tenaculum is a device that pinches to hold the cervix together, so we use two tenaculums to make sure we had a good seal as well.

Q Okay, sir. So just to make sure I've got my arms around all of it, the ways that you can develop a leak around the cervix is, A, the cervical canal could be too large to form a proper seal around the sheath. Correct?

A Right.

Q And then two is placing the sheath in the uterus incorrectly?

A Right.

Q And then the third would be if there were some movement associated during the procedure where a leak could develop around the sheath —

A Correct.

Q — in the cervix. Right?

A Right.

Q Okay. Let's take these one at a time.

You said you knew that the sheath was placed properly, and part of that is because you had the benefit of the hysteroscope and you could see where it was positioned. Correct?

A Correct.

Q Okay. Now, tell me about — what, if anything, do you know about the — about there being a fit with the sheath in Ms. Hughes's cervix? Did it fit properly or was there a seal there?

A Yeah. Based on the fact that in the testing phase or in the warmup phase part of that is to make sure that there's a device that's attached to that. It's a graduated cylinder that — like I said, this is a closed system that the fluid flows through.

And part of that is a graduated cylinder that measures any fluid changes in that system. And if there is a leak, if there is a change in the amount of fluid that's in that system, which would indicate a leak, then it's noted in that cylinder.

So somebody watches that cylinder to watch for that. And as I said, during the preheating phase and through eight of the ten minutes of the ablation procedure itself, that level was maintained.

So to that point we would say yes, we were in a proper position without a leakage.

Q Okay. And if there were an issue with the size of the cervix, my understanding of your testimony is that that's the reason you have a testing phase, to determine —

A Sure.

Q — whether there is a problem with the —

A I mean, all of these procedures go through a testing phase to — and it's not only — yeah, to test for whatever kind of leak, whether or not it be perforation or the cervix that, you know, you can't get a seal around.

Q If there was an issue with the cervix, it would have been detected at the testing phase. Correct?

A Should have been, yes.

Q Now let's go to this third area that you mentioned, movement of, I guess, the scope and the sheath during the procedure.

A Correct.

Q Was there any movement in the scope or the sheath during Ms. Hughes's procedure?

A No, no. And we even — because that's such, you know, an important element of doing the procedure properly, we even have the — we do this

procedure sitting down.

And we actually, you know, devised a stool that had an armrest on the front of it so that for ten minutes we didn't have to hold our hands up in the air. We literally were propped and braced so that no movement would take place. We had come up with a way to make sure there was no movement by anything.

So we had a stool with an armrest on it so that when we were in position and that thing started, we were sitting still. We didn't have to worry about arm fatigue, getting tired from trying to hold this thing up and in the right position.

So there was no movement at all in the patient when this happened. We were all — like I said, eight of the ten minutes into it everything is perfectly fine. We're looking good. And then, you know, again the fluid that — beeped, the warning kind of out of nowhere.

Q And how many folks were present in the OR during the procedure?

A I'm not sure, but there would have been at least four people present, maybe more.

Q All right, sir. Now, the stool with the pad, that's something that you can't — that — or —

A That's something we did.

Q — something that y'all came up with.

A That's not something that Boston Scientific said we had to do.

But, you know, they pointed out the fact that, "By the way, you know, you have to be real still with this."

So I'm not sure if that's — and he may have suggested doing something like that. I don't remember.

But, I mean, if you read the product manual or whatever, I don't remember there ever being anything saying you got to have a special chair for this or anything like that. This was just something we did to do it.

Q Okay. Now I want to talk to you about — there was some testimony about Boston Scientific making known certain risks for injury as a result of leakage.

A Yeah.

Q And the three risks that you just discussed with me, are those the risks that Boston Scientific brought to your attention and are there others?

A I mean, through the teaching phase and

through reading the — you know, the stuff I was provided with before we did it, that was where my knowledge of these being risks came from.

Of course, doing hysteroscopy, which, you know — ultimately the hydrothermal ablation is a hysteroscopic procedure. Nothing more. And the fluid is just diverted into a different avenue where it's heated and flows back through again.

And the inherent risk to hysteroscopy itself would be perforation. Now, you know, in most diagnostic hysteroscopies the system is open, which means we openly allow the fluid to leak out and drain, you know, because it allows for flow.

This is a closed system, but it's closed specifically to make sure that we keep up with that fluid because it's heated.

And in terms of other injury besides those, there may be some, but those are the ones that I'm the most — was the most aware of.

Q Right. Well, as part of your training on the device, they would have told you —

A Yeah, yeah.

Q — things about like, one, you got to make sure that the sheath is properly in place?

A Right. They were very specific. I have

to say I felt real comfortable with the training that we got on it.

Q Right.

A They were very pointed about saying, Here's the areas of concern, here's where you need to be careful, and here's where you can get into trouble.

Q And they would have also, I would assume, equally have told you to be certain that you have a proper seal?

A Yes. Oh, absolutely.

Q Okay. And they would also have told you to make sure that you don't move?

A Yes, sir.

Q Okay, sir.

A Those three things we were very specifically pointed at, and I can honestly say without reservation that I felt like all three of those things took place in this case.

Q Okay, sir. All right.

I think you've testified to this, and I think — correct me if I'm wrong: You don't remember any other specific things that Boston Scientific told you to look out for in terms of leakage?

That's an open-ended question.

A Yeah.

Q If you don't —

A I don't believe so, no.

Q Okay. So it would be fair to say, then, would it not, that they didn't warn you of a risk of there being some type of circuit board failure with the device?

MS. LEDFORD: Object to form.

BY MR. BLACKWOOD:

Q You remember anything like that?

A I don't ever recall them specifically mentioning malfunction of the device like that.

Q In fact, they would not have warned you of the risk of any type of malfunction with the device, would they?

MS. LEDFORD: Object to the form.

A I'm sorry. Could you read that back or repeat it?

BY MR. BLACKWOOD:

Q The types of things they warned you about were the three things that we just discussed versus warning you of some malfunction in the device?

A I was not specifically warned about malfunction of the device, no, or there being a history of a malfunction in the device.

Q And would it be fair to say you assumed that there wouldn't be a malfunction in the device?

A Right. No. I would obviously have taken objection to using something that I thought was going to fail on me in the middle of a procedure.

Q Right. The Novasure product that you discussed a little while ago —

A Yeah.

Q — you said that there was the risk of a thermal injury.

A Right. Burn.

Q A burn?

A Right.

Q How would a burn from a Novasure product manifest itself?

A Well, the same kind of way: If there's a perforation and that device were to come into contact with something other than the endometrium, it's going to burn it that way.

Q Is there liquid —

A No.

Q — in the Novasure device?

A No. We do a diagnostic hysteroscopy to begin with, so you distend the uterus with saline; but then that fluid is removed. So there may be

traces of fluid there, but the fluid itself is not heated. The device itself is solid, and it fits into the uterine cavity that way.

Q Okay. So if there were to be a burn with the Novasure product, would it be limited to the area that it was inserted when the device was activated?

A My assumption, barring there being some kind of electrical injury through insulation issues or whatever, is that the injury would be limited to that portion of the device which is the end of it that carries the electrical current, the bipolar part of it.

Q Okay. So there is no part of the Novasure product that has a liquid that could escape and burn other parts of the body?

A Correct. That's the difference, right.

Q One other question.

MR. BLACKWOOD: No. I think that's all, Dr. Weber. Thank you very much for your time.

FURTHER EXAMINATION BY MS. LEDFORD:

Q I just have one — Mr. Blackwood just asked you several questions and in doing so mentioned a malfunction of the device.

I know I previously asked you this, but

are you claiming that this device malfunctioned in your opinion?

A No.

Q Okay.

A My claim is that I don't know if it malfunctioned or not. I think I said that earlier, and —

MR. WILLIAMSON: You did.

A — I don't know if it malfunctioned or not.

MR. BANKS: I didn't want to interrupt your deposition. I just had a quick question.

A Sure.

EXAMINATION BY MR. BANKS:

Q Earlier you testified, I believe, that the procedure with relation to Ms. Jan and the Novasure procedure, that each had their own benefits and risks associated with them. Can you just compare and contrast the two.

A Sure. Well, we'll start with the hydrothermal ablation which uses the liquid.

To me the benefit of that is the liquid will go into any perceived space. So if there happened to be minor irregularities of the uterine cavity, a liquid is going to fill those spaces as

opposed to irregularities, in which case it wouldn't.

The other option that I particularly liked about the Boston Scientific is that you were watching the procedure as it took place. The hysteroscope was in the uterine cavity, and you could literally watch the tissue blanch. You were visualizing the procedure as it took place.

The obvious disadvantage to the hydrothermal ablation would be thermal injury due to leakage. That goes without saying.

The Novasure device, the advantages to it are its relative ease of use. It's a less timely procedure. You know, you don't have to worry so much about movement.

Its disadvantages are that it's a solid device, which means if there are irregularities in the uterine cavity, it would be less likely to pick those up.

And the other part is that contrary to the hydrothermal ablation, it's performed blindly basically. You put the hysteroscope in, you look around, you take the hysteroscope out and replace it with the hydrothermal ablation. So while you're ablating, you're not looking at what you're doing.

It's in there doing its thing by itself,

and that would be, to me, the disadvantage of it, is not being able to visualize the procedure while it's taking place.

Q Is there any reason before you go in that you have any reason to know about there being irregularities?

A Well, most of the time these patients have usually had ultrasounds or some sort of preoperative technique that would — what we're usually talking about are leiomyomas or fibroid tumors.

And if the fibroids are big enough and if they distort the uterine cavity, obviously that can be a problem. Most of the time we're pretty aware of that.

And if we think the patient has large fibroids, usually greater than four centimeters or so, if they have large fibroids, we're usually going to talk about doing another procedure anyway.

So we generally are aware of those things before we get there. I've never been surprised when I went in to do one that we found something we weren't looking for hysteroscopically.

MR. BANKS: All right. That's it.

(Deposition concluded at 11:00 a.m.)

CERTIFICATE OF COURT REPORTER

I, SHARRA REND, Certified Shorthand Reporter and Notary Public in and for the County of Lamar, State of Mississippi, hereby certify that the above and foregoing pages, and including this page, contain a full, true and correct transcript of the testimony of MICHAEL WEBER, MD as taken by me at the time and place heretofore stated in the aforementioned matter and later reduced to typewritten form by me to the best of my skill and ability.

I further certify that I placed the witness under oath to truthfully answer all questions in this matter under the authority vested by the State of Mississippi.

I further certify that I am not in the employ of or related to any counsel or party in this matter and have no interest, monetary or otherwise, as to the final outcome of this proceeding.

WITNESS MY SIGNATURE AND SEAL, this the 15th day of December, 2008.

SHARRA REND, CSR #1277
My commission expires:
August 2012